AMENDED IN ASSEMBLY JUNE 19, 2012

AMENDED IN SENATE JANUARY 4, 2012

AMENDED IN SENATE MARCH 24, 2011

SENATE BILL No. 289

Introduced by Senator Hernandez

February 14, 2011

An act to amend ~~Section 14105.28~~ *Sections 1206, 1222.5, and 2069* of the ~~Welfare and Institutions~~ *Business and Professions* Code, relating to ~~Medi-Cal~~ *healing arts*.

LEGISLATIVE COUNSEL'S DIGEST

SB 289, as amended, Hernandez. ~~Medi-Cal: inpatient hospital reimbursement methodology.~~ *Clinical laboratory techniques: training and instruction.*

Existing law provides for the licensure and regulation of clinical laboratories and various clinical laboratory health care professionals by the State Department of Health Care Services. Existing law authorizes the department to approve schools seeking to provide instruction in clinical laboratory techniques, as specified.

This bill would authorize the department to approve specified institutions seeking to provide instruction in clinical laboratory techniques, as specified, including, among others, a California licensed clinical laboratory and an accredited college or university in the United States. The bill would provide that a college or university holding a specified accreditation shall not be required to obtain separate approval for clinical training sites, as defined, if certain requirements are met.

The bill would also make technical, nonsubstantive changes to these provisions.

~~Existing law provides for the Medi-Cal program, which is administered by the State Department of Health Care Services and under which qualified low-income persons receive health care benefits. The Medi-Cal program is, in part, governed and funded by federal Medicaid Program provisions.~~

~~Existing law requires the department, subject to federal approval, to develop and implement a Medi-Cal payment methodology based on diagnosis-related groups that reflects the costs and staffing levels associated with quality of care for patients in all general acute care hospitals, as specified. Existing law requires the department to submit status reports to the Legislature on the implementation of these provisions, and requires the methodology to be implemented on July 1, 2012, or on the date that the Director of Health Care Services executes a specified declaration, whichever is later.~~

~~This bill would require the department to include prescribed information in the status reports submitted to the Legislature, and would make other technical, nonsubstantive changes to these provisions.~~

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 1206 of the Business and Professions Code is amended to read:

1206. (a) For the purposes of this chapter the following definitions are applicable:

(1) "Analyte" means the substance or constituent being measured including, but not limited to, glucose, sodium, or theophyline, or any substance or property whose presence or absence, concentration, activity, intensity, or other characteristics are to be determined.

~~(1)~~

(2) "Biological specimen" means any material that is derived from the human body.

~~(2)~~

(3) "Blood electrolyte analysis" means the measurement of electrolytes in a blood specimen by means of ion selective electrodes on instruments specifically designed and manufactured for blood gas and acid-base analysis.

~~(3)~~

(4) "Blood gas analysis" means a clinical laboratory test or examination that deals with the uptake, transport, and metabolism of oxygen and carbon dioxide in the human body.

~~(4)~~

(5) "Clinical laboratory test or examination" means the detection, identification, measurement, evaluation, correlation, monitoring, and reporting of any particular analyte, entity, or substance within a biological specimen for the purpose of obtaining scientific data which may be used as an aid to ascertain the presence, progress, and source of a disease or physiological condition in a human being, or used as an aid in the prevention, prognosis, monitoring, or treatment of a physiological or pathological condition in a human being, or for the performance of nondiagnostic tests for assessing the health of an individual.

~~(5)~~

(6) "Clinical laboratory science" means any of the sciences or scientific disciplines used to perform a clinical laboratory test or examination.

~~(6)~~

(7) "Clinical laboratory practice" means the application of clinical laboratory sciences or the use of any means that applies the clinical laboratory sciences within or outside of a licensed or registered clinical laboratory. Clinical laboratory practice includes consultation, advisory, and other activities inherent to the profession.

~~(7)~~

(8) "Clinical laboratory" means any place used, or any establishment or institution organized or operated, for the performance of clinical laboratory tests or examinations or the practical application of the clinical laboratory sciences. That application may include any means that applies the clinical laboratory sciences.

(9) "Clinical training site" means any place, establishment, or institution used by a department-approved program for the training of clinical laboratory scientists or limited clinical laboratory scientists to conduct training or instruction of licensed trainees or phlebotomy students in clinical laboratory practice, techniques, theory, or other training required pursuant to this chapter.

~~(8)~~

(10) "Direct and constant supervision" means personal observation and critical evaluation of the activity of unlicensed laboratory personnel by a physician and surgeon, or by a person licensed under this chapter other than a trainee, during the entire time that the unlicensed laboratory personnel are engaged in the duties specified in Section 1269.

(11) "Direct and responsible supervision" means both of the following:

(A) Personal observation and critical evaluation of the activity of a trainee by a physician and surgeon, or by a person licensed under this chapter other than a trainee, during the entire time that the trainee is performing clinical laboratory tests or examinations.

(B) Personal review by the physician and surgeon or the licensed person of all results of clinical laboratory testing or examination performed by the trainee for accuracy, reliability, and validity before the results are reported from the laboratory.

(12) "Licensed laboratory" means a clinical laboratory licensed pursuant to paragraph (1) of subdivision (a) of Section 1265.

~~(9)~~

(13) "Location" means either a street and city address, or a site or place within a street and city address, where any of the clinical laboratory sciences or scientific disciplines are practiced or applied, or where any clinical laboratory tests or examinations are performed.

~~(10)~~

(14) "Physician office laboratory" means a clinical laboratory that is licensed or registered under Section 1265, and that is either: (A) a clinical laboratory that is owned and operated by a partnership or professional corporation that performs clinical laboratory tests or examinations only for patients of five or fewer physicians and surgeons or podiatrists who are shareholders, partners, or employees of the partnership or professional corporation that owns and operates the clinical laboratory; or (B) a clinical laboratory that is owned and operated by an individual licensed physician and surgeon or a podiatrist, and that performs clinical laboratory tests or examinations only for patients of the physician and surgeon or podiatrist who owns and operates the clinical laboratory.

(15) "Point-of-care laboratory testing device" means a portable laboratory testing instrument to which the following applies:

(A) It is used within the proximity of the patient for whom the test or examination is being conducted.

(B) It is used in accordance with the patient test management system, the quality control program, and the comprehensive quality assurance program established and maintained by the laboratory pursuant to paragraph (2) of subdivision (d) of Section 1220.

(C) It meets the following criteria:

(i) Performs clinical laboratory tests or examinations classified as waived or of moderate complexity under the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA) (42 U.S.C. Sec. 263a).

(ii) Performs clinical laboratory tests or examinations on biological specimens that require no preparation after collection.

(iii) Provides clinical laboratory tests or examination results without calculation or discretionary intervention by the testing personnel.

(iv) Performs clinical laboratory tests or examinations without the necessity for testing personnel to perform calibration or maintenance, except resetting pursuant to the manufacturer's instructions or basic cleaning.

~~(11)~~

(16) "Public health laboratory" means a laboratory that is operated by a city or county in conformity with Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code and the regulations adopted thereunder.

(17) "Registered laboratory" means a clinical laboratory registered pursuant to paragraph (2) of subdivision (a) of Section 1265.

~~(12)~~

(18) "Specialty" means histocompatibility, microbiology, diagnostic immunology, chemistry, hematology, immunohematology, pathology, genetics, or other specialty specified by regulation adopted by the department.

~~(13)~~

(19) "Subspecialty" for purposes of microbiology, means bacteriology, mycobacteriology, mycology, parasitology, virology, molecular biology, and serology for diagnosis of infectious diseases, or other subspecialty specified by regulation adopted by the department; for purposes of diagnostic immunology, means

syphilis serology, general immunology, or other subspecialty specified by regulation adopted by the department; for purposes of chemistry, means routine chemistry, clinical microscopy, endocrinology, toxicology, or other subspecialty specified by regulation adopted by the department; for purposes of immunohematology, means ABO/Rh Type and Group, antibody detection for transfusion, antibody detection nontransfusion, antibody identification, compatibility, or other subspecialty specified by regulation adopted by the department; for pathology, means tissue pathology, oral pathology, diagnostic cytology, or other subspecialty specified by regulation adopted by the department; for purposes of genetics, means molecular biology related to the diagnosis of human genetic abnormalities, cytogenetics, or other subspecialty specified by regulation adopted by the department.

~~(14) "Direct and responsible supervision" means both of the following:~~

~~(A) Personal observation and critical evaluation of the activity of a trainee by a physician and surgeon, or by a person licensed under this chapter other than a trainee, during the entire time that the trainee is performing clinical laboratory tests or examinations.~~

~~(B) Personal review by the physician and surgeon or the licensed person of all results of clinical laboratory testing or examination performed by the trainee for accuracy, reliability, and validity before the results are reported from the laboratory.~~

~~(15) "Licensed laboratory" means a clinical laboratory licensed pursuant to paragraph (1) of subdivision (a) of Section 1265.~~

~~(16) "Registered laboratory" means a clinical laboratory registered pursuant to paragraph (2) of subdivision (a) of Section 1265.~~

~~(17) "Point-of-care laboratory testing device" means a portable laboratory testing instrument to which the following applies:~~

~~(A) It is used within the proximity of the patient for whom the test or examination is being conducted.~~

~~(B) It is used in accordance with the patient test management system, the quality control program, and the comprehensive quality assurance program established and maintained by the laboratory pursuant to paragraph (2) of subdivision (d) of Section 1220.~~

~~(C) It meets the following criteria:~~

~~(i) Performs clinical laboratory tests or examinations classified as waived or of moderate complexity under CLIA.~~

~~(ii) Performs clinical laboratory tests or examinations on biological specimens that require no preparation after collection.~~

~~(iii) Provides clinical laboratory tests or examination results without calculation or discretionary intervention by the testing personnel.~~

~~(iv) Performs clinical laboratory tests or examinations without the necessity for testing personnel to perform calibration or maintenance, except resetting pursuant to the manufacturer's instructions or basic cleaning.~~

~~(18) "Analyte" means the substance or constituent being measured including, but not limited to, glucose, sodium, or theophyline, or any substance or property whose presence or absence, concentration, activity, intensity, or other characteristics are to be determined.~~

(b) Nothing in this chapter shall restrict, limit, or prevent any person licensed to provide health care services under the laws of this state, including, but not limited to, licensed physicians and surgeons and registered nurses, from practicing the profession or occupation for which he or she is licensed.

(c) Nothing in this chapter shall authorize any person to perform or order health care services, or utilize the results of the clinical laboratory test or examination, unless the person is otherwise authorized to provide that care or utilize the results. The inclusion of a person in Section 1206.5 for purposes of performing a clinical laboratory test or examination shall not be interpreted to authorize a person, who is not otherwise authorized, to perform venipuncture, arterial puncture, or skin puncture.

SEC. 2. Section 1222.5 of the Business and Professions Code is amended to read:

1222.5. *(a)* The department may approve ~~schools~~ *any of the following* seeking to provide instruction in clinical laboratory technic which in the judgment of the department will provide instruction adequate to prepare individuals to meet the requirements for licensure or performance of duties under this chapter and regulations of the ~~department. The department shall establish by regulation the ratio of licensed clinical laboratory scientists to licensed trainees on the staff of the laboratory approved as a school and the minimum requirements for training in any specialty or in~~

~~the entire field of clinical laboratory science or practice. Application for approval shall be made on forms provided by the department.~~ *department:*

(1) A California licensed clinical laboratory.

(2) An accredited college or university in the United States of America.

(3) A United States military medical laboratory specialist program of at least 52 weeks duration.

(4) A laboratory owned and operated by the United States government.

(b) A college or university holding valid accreditation by the National Accrediting Agency for Clinical Laboratory Sciences that meets the requirements of subdivision (a) shall not be required to obtain separate approval for a clinical training site, provided that the clinical training site has obtained certification under the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA) (42 U.S.C. Sec. 263a).

(c) The department shall establish by regulation the ratio of licensed clinical laboratory scientists to licensed trainees on the staff of the clinical training site and the minimum requirements for training in any specialty or in the entire field of clinical laboratory science or practice. Application for approval shall be made on forms provided by the department.

SEC. 3. Section 2069 of the Business and Professions Code is amended to read:

2069. (a) (1) Notwithstanding any other provision of law, a medical assistant may administer medication only by intradermal, subcutaneous, or intramuscular injections and perform skin tests and additional technical supportive services upon the specific authorization and supervision of a licensed physician and surgeon or a licensed podiatrist. A medical assistant may also perform all these tasks and services in a clinic licensed pursuant to subdivision (a) of Section 1204 of the Health and Safety Code upon the specific authorization of a physician assistant, a nurse practitioner, or a nurse-midwife.

(2) The supervising physician and surgeon at a clinic described in paragraph (1) may, at his or her discretion, in consultation with the nurse practitioner, nurse-midwife, or physician assistant provide written instructions to be followed by a medical assistant in the performance of tasks or supportive services. These written

instructions may provide that the supervisory function for the medical assistant for these tasks or supportive services may be delegated to the nurse practitioner, nurse-midwife, or physician assistant within the standardized procedures or protocol, and that tasks may be performed when the supervising physician and surgeon is not onsite, so long as the following apply:

(A) The nurse practitioner or nurse-midwife is functioning pursuant to standardized procedures, as defined by Section 2725, or protocol. The standardized procedures or protocol shall be developed and approved by the supervising physician and surgeon, the nurse practitioner or nurse-midwife, and the facility administrator or his or her designee.

(B) The physician assistant is functioning pursuant to regulated services defined in Section 3502 and is approved to do so by the supervising physician or surgeon.

(b) As used in this section and Sections 2070 and 2071, the following definitions shall apply:

(1) "Medical assistant" means a person who may be unlicensed, who performs basic administrative, clerical, and technical supportive services in compliance with this section and Section 2070 for a licensed physician and surgeon or a licensed podiatrist, or group thereof, for a medical or podiatry corporation, for a physician assistant, a nurse practitioner, or a nurse-midwife as provided in subdivision (a), or for a health care service plan, who is at least 18 years of age, and who has had at least the minimum amount of hours of appropriate training pursuant to standards established by the Division of Licensing. The medical assistant shall be issued a certificate by the training institution or instructor indicating satisfactory completion of the required training. A copy of the certificate shall be retained as a record by each employer of the medical assistant.

(2) "Specific authorization" means a specific written order prepared by the supervising physician and surgeon or the supervising podiatrist, or the physician assistant, the nurse practitioner, or the nurse-midwife as provided in subdivision (a), authorizing the procedures to be performed on a patient, which shall be placed in the patient's medical record, or a standing order prepared by the supervising physician and surgeon or the supervising podiatrist, or the physician assistant, the nurse practitioner, or the nurse-midwife as provided in subdivision (a),

authorizing the procedures to be performed, the duration of which shall be consistent with accepted medical practice. A notation of the standing order shall be placed on the patient's medical record.

(3) "Supervision" means the supervision of procedures authorized by this section by the following practitioners, within the scope of their respective practices, who shall be physically present in the treatment facility during the performance of those procedures:

(A) A licensed physician and surgeon.

(B) A licensed podiatrist.

(C) A physician assistant, nurse practitioner, or nurse-midwife as provided in subdivision (a).

(4) "Technical supportive services" means simple routine medical tasks and procedures that may be safely performed by a medical assistant who has limited training and who functions under the supervision of a licensed physician and surgeon or a licensed podiatrist, or a physician assistant, a nurse practitioner, or a nurse-midwife as provided in subdivision (a).

(c) Nothing in this section shall be construed as authorizing the licensure of medical assistants. Nothing in this section shall be construed as authorizing the administration of local anesthetic agents by a medical assistant. Nothing in this section shall be construed as authorizing the division to adopt any regulations that violate the prohibitions on diagnosis or treatment in Section 2052.

(d) Notwithstanding any other provision of law, a medical assistant may not be employed for inpatient care in a licensed general acute care hospital as defined in subdivision (a) of Section 1250 of the Health and Safety Code.

(e) Nothing in this section shall be construed as authorizing a medical assistant to perform any clinical laboratory test or examination for which he or she is not authorized by Chapter 3 (commencing with Section 1206.5). Nothing in this section shall be construed as authorizing a nurse practitioner, nurse-midwife, or physician assistant to be a laboratory director of a clinical laboratory, as those terms are defined in paragraph ~~(7)~~ *(8)* of subdivision (a) of Section 1206 and subdivision (a) of Section 1209.

~~SECTION 1. Section 14105.28 of the Welfare and Institutions Code is amended to read:~~

~~14105.28. (a) It is the intent of the Legislature to design a new Medi-Cal inpatient hospital reimbursement methodology based on diagnosis-related groups that more effectively ensures all of the following:~~

~~(1) Encouragement of access by setting higher payments for patients with more serious conditions.~~

~~(2) Rewards for efficiency by allowing hospitals to retain savings from decreased length of stays and decreased costs per day.~~

~~(3) Improvement of transparency and understanding by defining the "product" of a hospital in a way that is understandable to both clinical and financial managers.~~

~~(4) Improvement of fairness so that different hospitals receive similar payment for similar care and payments to hospitals are adjusted for significant cost factors that are outside the hospital's control.~~

~~(5) Encouragement of administrative efficiency and minimizing administrative burdens on hospitals and the Medi-Cal program.~~

~~(6) That payments depend on data that has high consistency and credibility.~~

~~(7) Simplification of the process for determining and making payments to the hospitals.~~

~~(8) Facilitation of improvement of quality and outcomes.~~

~~(9) Facilitation of implementation of state and federal provisions related to hospital acquired conditions.~~

~~(10) Support of provider compliance with all applicable state and federal requirements.~~

~~(b) (1) (A) (i) The department shall develop and implement a payment methodology based on diagnosis-related groups, subject to federal approval, that reflects the costs and staffing levels associated with quality of care for patients in all general acute care hospitals in state and out of state, including Medicare critical access hospitals, but excluding public hospitals, psychiatric hospitals, and rehabilitation hospitals, which include alcohol and drug rehabilitation hospitals.~~

~~(ii) The payment methodology developed pursuant to this section shall be implemented on July 1, 2012, or on the date upon which the director executes a declaration certifying that all necessary federal approvals have been obtained and the methodology is sufficient for formal implementation, whichever is later.~~

~~(B) The diagnosis-related group-based payments shall apply to all claims, except claims for psychiatric inpatient days, rehabilitation inpatient days, managed care inpatient days, and swing bed stays for long-term care services, provided, however, that psychiatric and rehabilitation inpatient days shall be excluded regardless of whether the stay was in a distinct-part unit. The department may exclude or include other claims and services as may be determined during the development of the payment methodology.~~

~~(C) Implementation of the new payment methodology shall be coordinated with the development and implementation of the replacement Medicaid Management Information System pursuant to the contract entered into pursuant to Section 14104.3, effective on May 3, 2010.~~

~~(2) The department shall evaluate alternative diagnosis-related group algorithms for the new Medi-Cal reimbursement system for the hospitals to which paragraph (1) applies. The evaluation shall include, but not be limited to, consideration of all of the following factors:~~

~~(A) The basis for determining diagnosis-related group base price, and whether different base prices should be used taking into account factors such as geographic location, hospital size, teaching status, the local hospital wage area index, and any other variables that may be relevant.~~

~~(B) Classification of patients based on appropriate acuity classification systems.~~

~~(C) Hospital case mix factors.~~

~~(D) Geographic or regional differences in the cost of operating facilities and providing care.~~

~~(E) Payment models based on diagnosis-related groups used in other states.~~

~~(F) Frequency of group updates for the diagnosis-related groups.~~

~~(G) The extent to which the particular grouping algorithm for the diagnosis-related groups accommodates the International Classification of Diseases, 10th Revision (ICD-10), diagnosis and procedure codes, and applicable requirements of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA; Public Law 104-191).~~

~~(H) The basis for calculating relative weights for the various diagnosis-related groups.~~

~~(I) Whether policy adjusters should be used, for which care categories they should be used, and the frequency of updates to the policy adjusters.~~

~~(J) The extent to which the payment system is budget neutral and can be expected to result in state budget savings in future years.~~

~~(K) Other factors that may be relevant to determining payments, including, but not limited to, add-on payments, outlier payments, capital payments, payments for medical education, payments in the case of early transfers of patients, and payments based on performance and quality of care.~~

~~(c) The department shall submit to the Legislature status reports on the implementation of this section on April 1, 2011, April 1, 2012, April 1, 2013, and April 1, 2014. The status reports submitted pursuant to this subdivision shall include a list of the claims and services excluded pursuant to subparagraph (B) of paragraph (1) of subdivision (b).~~

~~(d) The alternatives for a new system described in paragraph (2) of subdivision (b) shall be developed in consultation with recognized experts with experience in hospital reimbursement, economists, the federal Centers for Medicare and Medicaid Services, and other interested parties.~~

~~(e) In implementing this section, the department may contract, as necessary, on a bid or nonbid basis, for professional consulting services from nationally recognized higher education and research institutions, or other qualified individuals and entities not associated with a particular hospital or hospital group, with demonstrated expertise in hospital reimbursement systems. The rate setting system described in subdivision (b) shall be developed with all possible expediency. This subdivision establishes an accelerated process for issuing contracts pursuant to this section and contracts entered into pursuant to this subdivision shall be exempt from the requirements of Chapter 1 (commencing with Section 10100) and Chapter 2 (commencing with Section 10290) of Part 2 of Division 2 of the Public Contract Code.~~

~~(f) (1) The department may adopt emergency regulations to implement the provisions of this section in accordance with rulemaking provisions of the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code). The initial adoption~~

~~of emergency regulations and one readoption of the initial regulations shall be deemed to be an emergency and necessary for the immediate preservation of the public peace, health and safety, or general welfare. Initial emergency regulations and the one readoption of those regulations shall be exempt from review by the Office of Administrative Law. The initial emergency regulations and the one readoption of those regulations authorized by this section shall be submitted to the Office of Administrative Law for filing with the Secretary of State and publication in the California Code of Regulations.~~

~~(2) As an alternative to paragraph (1), and notwithstanding the rulemaking provisions of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, or any other provision of law, the department may implement and administer this section by means of provider bulletins, all-county letters, manuals, or other similar instructions, without taking regulatory action. The department shall notify the fiscal and appropriate policy committees of the Legislature of its intent to issue a provider bulletin, all-county letter, manual, or other similar instruction, at least five days prior to issuance. In addition, the department shall provide a copy of any provider bulletin, all-county letter, manual, or other similar instruction issued under this paragraph to the fiscal and appropriate policy committees of the Legislature.~~

O